

REMARKS

Claims 67-86 are pending and under examination. Claim 86 has been cancelled in this amendment without prejudice or disclaimer.

Double Patenting Rejection

The rejection of claims 67-69, 76 and 79 under the judicially created doctrine of obviousness-type double patenting as allegedly obvious over claim 1 of U.S. Patent No. 6,743,769, is respectfully traversed.

Additionally, the rejection of claims 67-69 under the judicially created doctrine of obviousness-type double patenting as allegedly obvious over claim 1 of U.S. Patent No. 7,067,621, is respectfully traversed.

Applicants respectfully request that these rejections be held in abeyance until there is an indication of allowable subject matter at which time Applicants will file a Terminal Disclaimer if appropriate.

Rejections under 35 U.S.C. § 112

Claim 86 stands rejected under 35 U.S.C. § 112, second paragraph for improper claim dependency. Claim 86 has been canceled herein, thus rendering this rejection moot. Withdrawal of this rejection is respectfully requested.

Rejections under 35 U.S.C. § 103

Applicants respectfully traverse the rejection of claims 67, 68, and 84 under 35 U.S.C. § 103(a), as allegedly being obvious over United States Patent No. 5,409,898, to Darveau *et al.*

Applicants respectfully point out the following deficiencies with regard to the aforementioned rejection: There is a lack of motivation (1) to pick a particular species from the genus of cationic oligopeptides taught by Darveau *et al.* and (2) to make the particular modifications necessary within a subgenus derived from this species to arrive at a particular overlapping species within the claimed genus of independent claim 67 as explained below.

The examiner bears the burden of establishing a *prima facie* case of obviousness. *In re Rijckaert*, 9 F.3d 1531, 1532, (Fed. Cir. 1993). Only if this burden is met does the burden of coming forward with rebuttal argument or evidence shift to the applicant. *Id.* When the references cited by the examiner fail to establish a *prima facie* case of obviousness, the rejection is improper and will be overturned. *In re Fine*, 837 F.2d 1071, 1074 (Fed. Cir. 1988).

To support a *prima facie* finding of obviousness, it is required that the prior art references must teach or suggest all the claim limitations. *In re Royka*, 490 F.2d 981, 985 (CCPA 1974). There must also be some guidance either in the references themselves or in the general knowledge of skill in the art to motivate combining the references. Further, there must be a reasonable expectation of success in the combination suggested. Applicants respectfully submit that the Examiner has presented insufficient evidence of *prima facie* obviousness.

The Examiner alleges that Darveau *et al.* disclose a cationic oligopeptide having the sequence Ala-Leu-Tyr-Lys-Lys-Leu-Leu-Lys-Lys-Leu-Leu-Lys-Ser-Ala-Lys-Lys-Leu-Gly and the like. (col. 7, lines 46-48, emphasis added, hereinafter species A). Furthermore, the Examiner alleges that Darveau *et al.* teaches a helix is formed that can be right- or left-handed and can incorporate non-protein amino acids such as alpha, alpha-dialkyl amino acids. (col. 10, lines 53-58).

Species A is a member of a broad genus taught by Darveau *et al.* having the formula aa1-Leu-Tyr-Lys-Lys-Lys-aa2-aa2-Lys-Lys-Leu-Leu-aa3-aa4-X, where aa1 is Pro, Ala, or Lys, aa2 is Ile or Leu, aa3 is Glu or Lys, aa4 is Ser, Leu or Lys, and X is a five amino acid sequence being alpha helical in nature, and having the general sequence of aa5-Lys-Lys-aa6-Gly, wherein aa5 is Ala or Leu, and aa6 is Leu or Phe. (col. 7, lines 16-25, hereinafter genus A) Thus, the first step in bridging the gap between genus A and the genus defined in independent claim 67 is to choose starting peptide species A. Applicants believe that there is no motivation to cherry pick species A out of the first broad genus among the myriad of disclosed species.

Even assuming *arguendo* that species A were chosen, there is a further bridge to gap. The Examiner has used the passage cited at column 10, lines 53-58 to create a subgenus (generated from species A) that allegedly overlaps with the genus of claim 67. Specifically, the Examiner alleges that the recitation in Darveau *et al.* that “the helix formed...can contain non-

protein amino acids (i.e. alpha, alpha-dialkyl amino acids,...” renders obvious the genus of claim 67 because one could swap out amino acids in positions 6 and/or 7 of the claimed genus with modified amino acids and this theoretical species could fall within the subgenus defined by substituting one or more modified amino acids in specie A. Applicants believe this logic is flawed for at least two reasons.

First, species A does not fall within the genus of claim 67, and the subgenus created from species A does not represent a reasonably finite set of compounds to suggest the necessary changes to arrive at those species that may overlap with claim 67. Moreover, there is no motivation in Darveau *et al.* to change the particular amino acid residues at positions 6 and/or 7 in the 18 amino acid sequence of species A. In the context of column 10, lines 55-58, the only apparent portions of species A for which there is a suggestion to exchange the naturally occurring amino acids for the non-protein amino acids are the alpha helical regions. The only region specifically defined as alpha helical in the genus at col. 7, lines 16-25 is portion X, which is a five amino acid sequence being alpha helical in nature, and having the general sequence of aa5-Lys-Lys-aa6-Gly. This does not correspond to positions 6 and/or 7, nor does Darveau indicate that this portion of the peptide is an alpha helical region.

Applicants therefore believe there is no motivation to make the changes in species A, at positions 6 and 7 as suggested by the Examiner, to arrive at theoretical species that overlap with the genus of claim 67. Thus, claim 67 should be patentable over Darveau *et al.* Claims 68-85 depend therefrom and should be patentable for at least the same reasons. Withdrawal of this rejection is respectfully requested.

In light of the remarks herein, Applicants submit that the claims are now in condition for allowance and respectfully request a notice to this effect. The Examiner is invited to call the undersigned agent if there are any questions.

Applicants note the Examiner's objection to claim 70-75, 77, 78, 80-83, and 85 because of their dependence on a claim currently under rejection.

Application No.: 09/648,816

To the extent necessary, a petition for an extension of time under 37 C.F.R. 1.136 is hereby made. Please charge any shortage in fees due in connection with the filing of this paper, including extension of time fees, to Deposit Account 502624 and please credit any excess fees to such deposit account.

Respectfully submitted,

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